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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,484	01/17/2006	Nai-Kong V. Cheung	639-C-PCT-US	2140

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,484	CHEUNG, NAI-KONG V.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17,19-25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17, 19-25, and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted March 10, 2009 wherein claims 14 and 22 are amended. This application is a national stage application of PCT/US04/23099, filed July 16, 2004, which is a continuation in part of US application 10/621027, currently pending, filed July 16, 2003, which is a continuation in part of PCT/US02/01276, filed January 15, 2002, which claims benefit of provisional application 60/261911, filed January 16, 2001.

Claims 14-17, 19-25, and 27-29 are pending in this application.

Claims 14-17, 19-25, and 27-29 as amended are examined on the merits herein.

Priority

Currently, the application claims priority to US application 10/621027, PCT international applications PCT/US04/23099 and PCT/US02/01276, and provisional application 60/261911. However, the applications PCT/US02/01276, 10/621027, and 60/261911 fail to provide written description under 35 USC 112, first paragraph for instant claims 14-17, 19-25, and 27-29 because the applications do not disclose beta-glucans having side chains of two or more saccharides linked by a (1,3) linkage. Rather, these parent applications disclose barley glucans having a straight chain containing a mixture of (1,3) and (1,4) linkages, as well as fungal glucans of indeterminate composition. Therefore the effective filing date of claims 14-17, 19-25, and 27-29, all of the currently pending claims, is seen to be the filing date of PCT/US04/23099, filed July 16, 2004.

Applicant's amendment, submitted March 10, 2009, with respect to the rejection of instant claims 14-17, 19-25, and 27-29 under 35 USC 102(e) for being anticipated by Ostroff et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the glucan be soluble, where the glucans of Ostroff et al. are necessarily insoluble. Therefore the rejection is withdrawn.

Applicant's amendment submitted March 10, 2009, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment submitted March 10, 2009 introduces new matter into the claims. Specifically, while the specification and the claims as originally filed disclose soluble beta (1,3)(1,6) glucans, and furthermore disclose other beta glucans (e.g.

grifolan) which can induce cytokines, the disclosure never specifically discloses soluble beta (1,3)(1,6) glucans that induce cytokines. One skilled in the art would take this absence to mean that Applicant was not in fact in possession of these cytokine inducing soluble beta (1,3)(1,6) glucans at the time of the invention, in view of the fact that the prior art teaches that these two properties are antagonistic to one another. Specifically, Ross et al. (US pre-grant publication 2006/0009419, cited in PTO-892) discloses in p. 1 paragraph 0007 and p. 15 paragraph 0132 that neutral soluble beta (1,3)(1,6) glucans prepared from yeast are too small to elicit cytokine release. Therefore one skilled in the art, in the absence of any disclosure in the application as originally filed addressing whether these glucans can elicit cytokine release, would not have regarded them as possessing such activity. Therefore the application does not provide written description for these claims. If Applicant disagrees, the response to this rejection should include an indication of where in the specification said written description can be found.

Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

> only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-16, 19-24, and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al. (US pre-grant publication 2006/0009419, cited in PTO-892)

Ross et al. discloses a neutral soluble beta (1,3) glucan and compositions of said glucan with complement activating tumor specific antibodies, including monoclonal antibodies. (p. 2 paragraph 0011) In certain embodiments, the antibody is selected from trastuzumab, rituximab, cetuxunab, and combinations thereof. (p. 3 paragraph 0016) According to the FDA-approved labeling for these antibodies, (References of record in previous action, included solely to elucidate the teaching of Ross et al. and not as a secondary reference) trastuzumab binds to the protein HER2 (p. 1 last paragraph of label) and is used to treat metastatic breast cancer, (p. 4 paragraph 4 of label) rituximab binds CD20 (p. 1 left column fourth paragraph of label) and is used to treat non-Hodgkin's lymphoma, (p. 1 right column third paragraph of label) and cetuxumab binds the protein EGFR (p. 1 first paragraph of label) and is used to treat colorectal carcinoma. (p. 6 second paragraph of label) The glucans include polymers having beta (1,3) and (1,6) linkages that are derived from cell walls. (p. 6 paragraph 0009419) These glucans include neutral soluble glucans (p. 7 paragraph 0063) which are prepared from whole glucan particles, (p. 10 paragraphs 0092-0097) which are prepared from yeast including *Saccharomyces cerevisiae*. (p. 7 paragraphs 0064-0065) *S. cerevisiae* beta glucan is disclosed to comprise a beta (1,3) backbone with periodic beta (1,3) side chains linked by beta (1,6) linkages. (p. 1 paragraph 0004). As the glucans described in the reference could be administered orally they are therefore

reasonably considered to be "orally administered compositions" according to the instant claims. Thus the neutral soluble glucans and antibodies described by the specification anticipate the claimed invention.

Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Conclusion

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
6/15/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623